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(54) **Sensor indicating and controlling substance concentration**

(57) A sensor 10 for producing a signal representative of the instantaneous amount of a substance in an environment e.g. hydrogen peroxide in a sterilization chamber, comprises a first element 18 for producing a first signal representative of the temperature T1 of the environment. The first element is isolated from the substance. A second element 12 includes a material which is capable of interacting with the substance to modify the temperature T2 sensed by the second element. The second element produces a second signal representative of the modified temperature such that the first and second signals are representative of the instantaneous amount of the concentrate in the environment. The sensor 10 may be used in a system for indicating the instantaneous amount of a substance in an environment or in a system for controlling the instantaneous amount of a substance in a chamber.

Fig. 1.

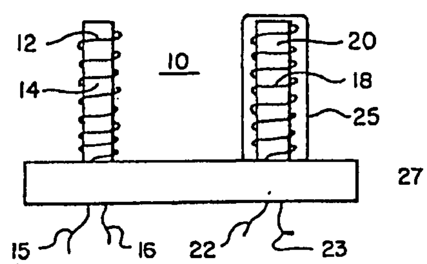

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Fig. 1.

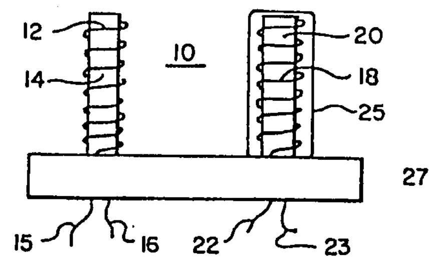
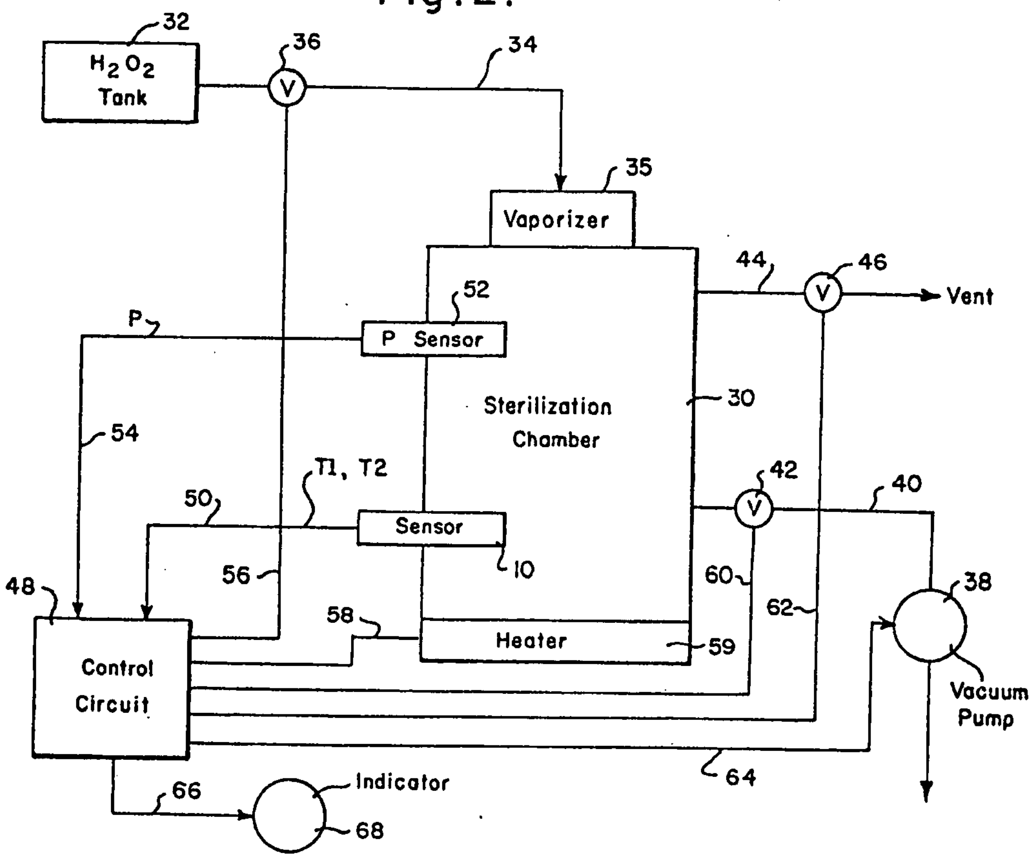

12
14
10
20
18
25
27
15
16
22
23

Fig. 2.


32
H_2O_2 Tank
36
V
34
35
Vaporizer
44
46
V
Vent
52
P
P Sensor
Sterilization Chamber
30
54
T1, T2
42
V
40
50
Sensor
10
56
60
62
38
48
58
Heater
59
Control Circuit
Vacuum Pump
64
66
Indicator
68

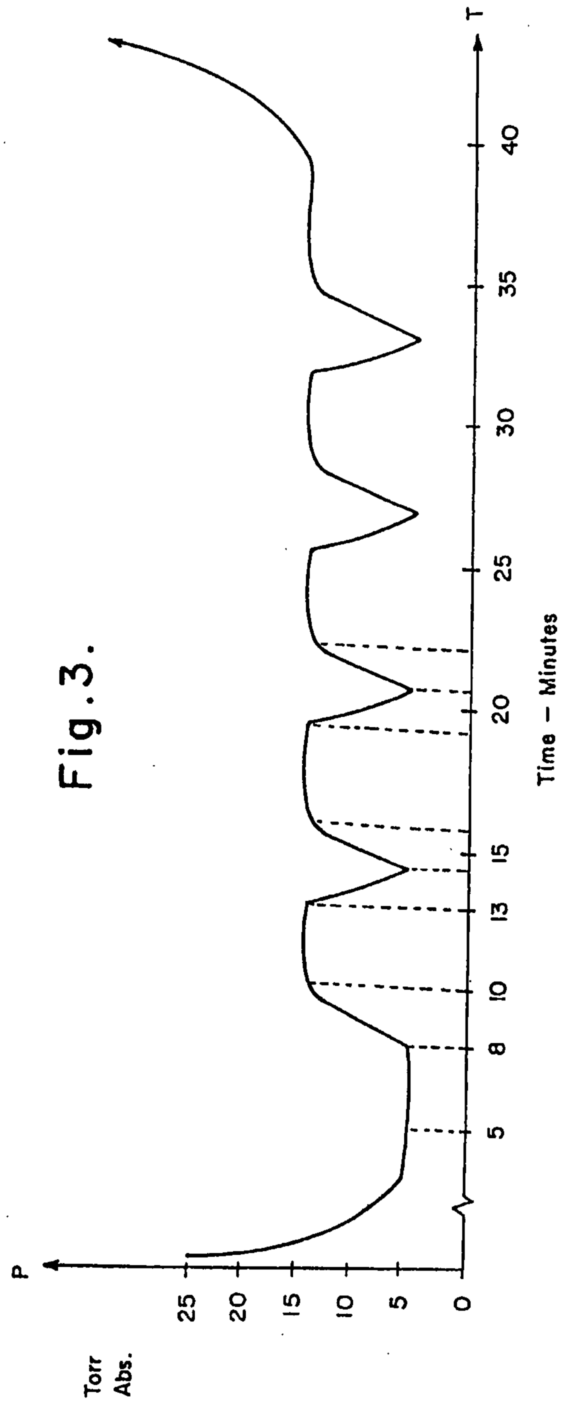


Fig.3.

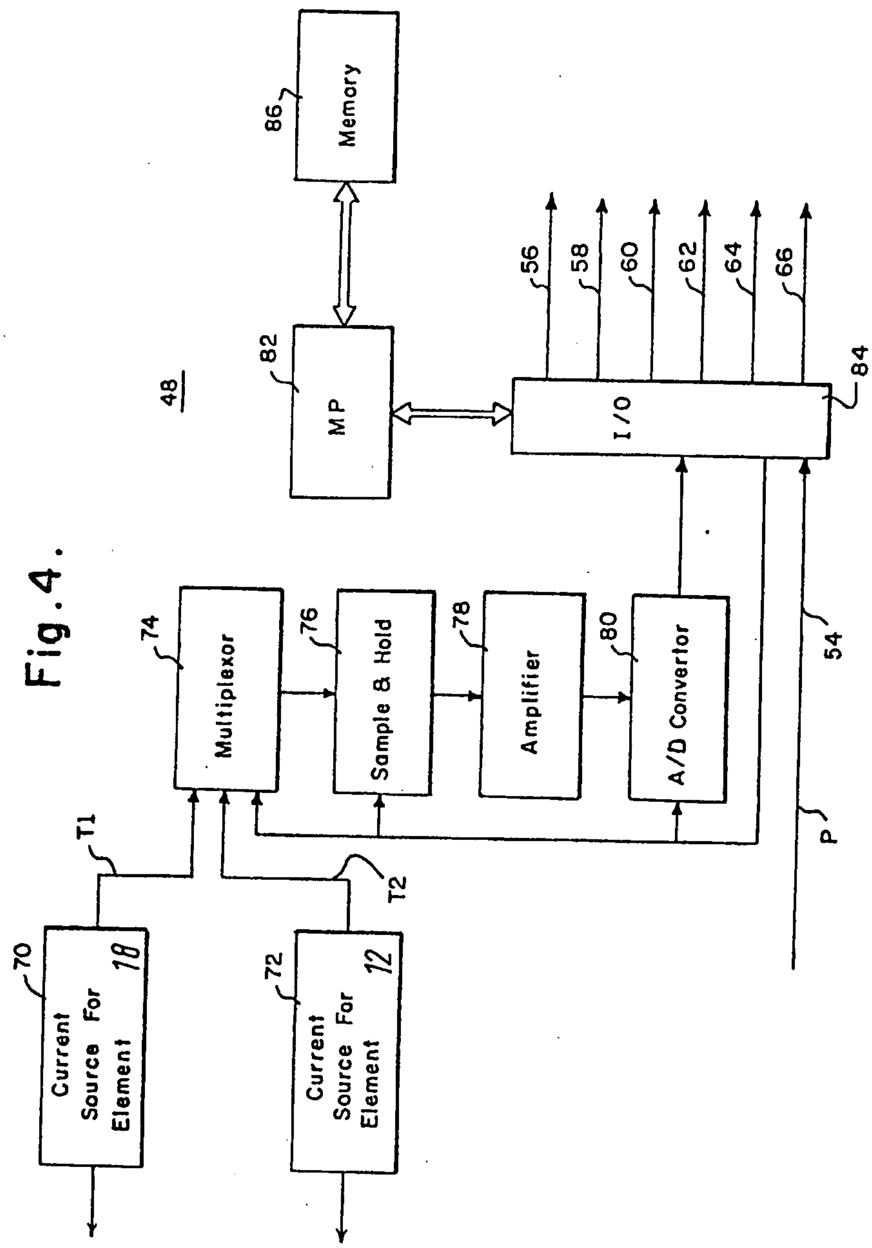

48
Memory
86
MP
82
I/O
84
56
58
60
62
64
66
Multiplexor
74
Sample & Hold
76
Amplifier
78
A/D Convertor
80
54
P
T1
T2
Current Source For Element 10
70
Current Source For Element 12
72

Fig. 4.

SPECIFICATION

Sensor, indicating system and control system

The present invention is related generally to sensors, and more particularly to sensors for providing an instantaneous indication of the amount of a substance (hereinafter referred to as a concentrate) in an environment. The invention also relates to a system for indicating the amount of concentrate in an environment and to a system of controlling the amount of a concentration in an environment.

In many applications, it is necessary to monitor continually the amount of a substance within an environment. For example, in sterilization chambers using vapour phase hydrogen peroxide for sterilization, it is important to monitor the concentration of the hydrogen peroxide within the chamber for the purposes of controlling the amount of hydrogen peroxide used and for verifying the sterilization atmosphere. Currently, there is no practical method of measuring directly the instantaneous amount or concentration of vapour phase hydrogen peroxide during a sterilization cycle although various methods currently exist for indirectly measuring the concentration of vapour phase hydrogen peroxide.

An example of indirect measurement techniques includes using the rise in pressure as an indication of the concentration of vapour phase hydrogen peroxide. However, the pressure reading may not be accurate due to the presence of water vapour which has similar properties. Biological testing which involves placing organisms in the sterilizer provides information that the concentration was high enough to kill the organisms, but not what the concentration was. Additionally, because of long incubation times and the associated load quarantine period, biological testing does not provide instantaneous readings.

Direct concentration measurement techniques, such as placing responsive or sensitive paper in the sterilizer, do not provide continuous measurements because the quantity of concentrate in the paper is cumulative. Methods relying on absorption of the sterilant into a carrier during all or part of the cycle followed by subsequent spectrometric analysis of the carrier cannot be used for control and are only marginally beneficial for verification. Directly taking samples of gas can lead to contamination problems which may cause the hydrogen peroxide to decompose into its constituent elements. Additionally, because the sterilizer is typically working at a deep vacuum, an even deeper vacuum is required to draw out a sample. Thus, there is a practical need for instantaneously measuring the amount of a sterilant in an environment for both controlling the amount of sterilant used as well as for verifying the proper sterilizing atmosphere.

The present invention in its broadest aspects is directed to a sensor for producing a signal representative of the instantaneous amount of a concentrate in an environment comprising first means for producing a first signal representative of the temperature of the environment;

shield means for isolating said first means from the concentrate; and

second means including a material capable of interacting with the concentrate to modify the temperature sensed by said second means, said second means serving for producing a second signal representative of said modified temperature such that said first and second signals are representative of the instantaneous amount of the concentrate in the environment.

The second means of the sensor may include a platinum resistance temperature detector capable of interacting with a hydrogen peroxide concentrate.

The sensor of the present invention may form the basis of a system for indicating the instantaneous amount of a concentrate in an environment. Such a system comprises a first resistive element isolated from the concentrate for producing a first signal representative of the temperature of the environment; second resistive element exposed to the concentrate and constructed of a material capable of interacting with the concentrate to modify the temperature sensed by the second resistive element, said second resistive element serving for producing a second signal representative of the modified temperature; means responsive to the first and second signals for producing an output signal representative of the instantaneous amount of concentrate in the environment; and an output device responsive to the output signal.

The system of the present invention for indicating the instantaneous amount of a concentrate may be used for controlling the instantaneous amount of a concentrate in a chamber. Such a control system comprises a first resistive element positioned in the chamber and isolated from the concentrate for producing a first signal representative of the temperature in the chamber; a second resistive element exposed to the concentrate and constructed of a material capable of interacting with the concentrate to modify the temperature sensed by the second resistive element, the second resistive element serving for producing a second signal representative of the modified temperature, said first and second signals being representative of the instantaneous amount of concentrate in the chamber; means for increasing the amount of concentrate in the chamber; means for decreasing the amount of concentrate in the chamber; and a control circuit responsive to the first and second signals for producing output signals for controlling the means for increasing the amount of concentrate in the chamber and the means for decreasing the amount of concentrate in the chamber such that the instantaneous amount of concentrate in the chamber is controlled.

The sensor and systems of the present invention enable the instantaneous amount of a concentrate to be precisely and continuously determined. Because of this, processes, such as sterilization cycles, may be monitored precisely for controlling the amount of sterilant used and to ensure sufficiently high sterilant concentrations over sufficiently long periods to ensure proper sterilization.

The present invention is further described, by way

of example, with reference to the accompanying drawings, wherein:

Figure 1 illustrates a sensor constructed according to the present invention;

Figure 2 illustrates a system for controlling the instantaneous amount of a concentrate in a chamber using the sensor of the present invention;

Figure 3 is a graph illustrating a typical known hydrogen peroxide sterilization cycle for wrapped microsurgical instruments; and

Figure 4 is a block diagram illustrating the components of the control circuit illustrated in Figure 2.

As shown in Figure 1, a sensor 10 constructed according to the present invention comprises a first resistive element 18 wound about a core 20. The first element 18 has a pair of leads 22 and 23 extending therefrom. A second resistive element 12 is wound in a spiral about a core 14. The second element 12 has a pair of leads 15 and 16 extending therefrom.

The first element 18 is enclosed in a thin, heat-transmissive, inert plastics or glass sleeve 25. The first element 18 and the second element 12 are held proximate to one another by a substrate 27. In an environment of air or water vapour, both elements 12 and 18 will measure the same temperature because of their proximity to one another. Some minimum time lag will be experienced by the first resistive element 18 due to the sleeve 25. However, that time lag is kept to a minimum by making the sleeve 25 very thin and of a material having good heat-transmissive properties.

The sensor 10 works on the principle that the resistive element 12 will interact with the concentrate being sensed. For example, if the second element 12 and the first element 18 are constructed of platinum, a concentrate, such as hydrogen peroxide vapour, will catalyze in the presence of the platinum of the exposed second element 12 and breakdown into its component parts, namely oxygen and water, while giving off heat according to well-known chemical equations. The first element 18 will measure the vapour temperature T1 only while the exposed second element 12 will measure a proportionally elevated temperature T2. The difference in the temperatures measured by the first element 18 and second element 12 is representative of the hydrogen peroxide vapour concentration.

The amount of platinum in element 12 should be kept small such that the amount of hydrogen peroxide vapour catalyzed will be small and will not sufficiently affect the overall hydrogen peroxide concentration in the chamber. The breakdown of the hydrogen peroxide vapour is an ongoing process and heat will continually be generated. The temperature of the second element 12 will rise slightly above ambient and give off heat to the surrounding area. By maintaining the overall amount of platinum in element 12 small, the heat given off to the surrounding area will not affect the temperature sensed by the first element 18. The temperature sensed by the second element 12 will eventually reach an equilibrium at a higher than ambient temperature which is proportional to the hydrogen peroxide vapour concentration. Additionally, the vapour concentration of the environment should be kept at or below saturation such that the water vapour by-product of the catalyzation process will remain vapourized and not foul the second element 12.

The foregoing principle is equally applicable to other types of concentrates providing that the second element 12 is constructed of a material capable of interacting with the concentrate to modify the temperature sensed by the second element 12. In addition, it is recognized that chemical reactions may result between certain sensors 12 and concentrates which may be reversible thereby enabling the sensors 12 to be rejuvenated or which may be irreversible thereby leading to consumption of the sensors 12.

As described above, the first element 18 measures the temperature T1 of the environment. The exposed second element 12 measures a higher temperature T2 as a result of the catalytic decomposition of the vapour phase hydrogen peroxide. This second temperature T2 is a function of the environmental temperature as well as the concentration of the vapour phase hydrogen peroxide as indicated by equation (1).

$$T2 = f1\,(T1, C) \ldots eq\,(1)$$

The sterilant concentration can be determined by rearranging equation (1) as follows:

$$C = f2\,(T1, T2) \ldots eq\,(2)$$

Equation (2) assumes a relatively constant operating pressure P. Otherwise, equation (2) can be generalized:

$$C = F3\,(T1, T2, P) \ldots eq\,(3)$$

In a practical application, the temperature of a sterilization chamber is controlled at 55°C and evacuated to 10mmHg absolute pressure (1.33 kPa, absolute), for example. Under these circumstances, T1 and P from equation (3) are constant and can thus be ignored. Equation (3) can then be simplified:

$$C = f4\,(T2 - T1) \ldots eq\,(4)$$

The simplified equation (4) applies only if operation is over a narrow range of temperatures and pressures. Otherwise, the more general equation (3) should be used.

A look-up or empirical table approximating the functions f3 and f4 can be generated. This is accomplished according to known procedures by exposing the sensor 10 to various known concentrations of vapour phase hydrogen peroxide. By holding the temperature T1 and pressure P constant, the f4 data is determined as a function of the difference of the two temperature readings. By varying the temperature T1 and pressure P1, the f3 data is determined as a function of the two temperatures and the pressure. Thus, appropriate look-up tables can be generated.

Figure 2 illustrates a control system using the sensor 10 of the present invention for controlling the amount of hydrogen peroxide in a sterilization chamber 30. The sterilization chamber 30 is connected to a hydrogen peroxide tank 32 through a line 34. The flow of hydrogen peroxide from the tank 32 to the sterilization chamber 30 throughh the line 34 is controlled by a valve 36.

The flow of material from the sterilization chamber 30 is controlled by a vacuum pump 38 connected to the sterilization chamber 30 through a line 40. The flow of material through the line 40 is controlled by a valve 42. The sterilization chamber 30 may also be vented through a vent line 44. The vent line 44 has a valve 46 for controlling the flow of material through the vent line 44.

The temperature signals T1 and T2 produced by the sensor 10 are input to a control circuit 48 through an input line 50. A pressure sensor 52 produces a signal representative of the pressure P which is input to the control circuit 48 through an input line 54. In response to this raw data, the control circuit 48 produces output signals as described further hereinbelow which are output on lines 56, 58, 60, 62 and 64 for controlling the operation of valve 36, a heater 59, the valve 42, the valve 46, and the vacuum pump 38, respectively. The control circuit may also produce an output signal output on line 66 to an indicator 68 for indicating the instantaneous value of the hydrogen peroxide concentration in the sterilization chamber 30.

The sterilization chamber 30 illustrated in Figure 2 may be operated according to any of various well-known sterilization cycles. A typical known hydrogen peroxide sterilization cycle used for wrapped microsurgical instruments is illustrated in Figure 3. The graph illustrated in Figure 3 shows that the variables during a sterilization cycle include the depth of the vacuum which is drawn in the sterilization chamber 30, the amount of hydrogen peroxide injected into the chamber per pulse, the hold time of each pulse, the number of pulses, the temperature within the sterilization chamber 30, and the concentration of the hydrogen peroxide sterilant.

In Figure 3, a vacuum is drawn in the sterilization chamber 30 for approximately the first eight minutes of the sterilization cycle during which time the sterilization chamber is heated. At approximately eight minutes into the cycle, hydrogen peroxide is injected into the sterilization chamber 30 which decreases the vacuum within the sterilization chamber 30. At approximately ten minutes into the sterilization cycle, the pressure within the sterilization chamber 30 stabilizes and is held for approximately three minutes. At thirteen minutes into the sterilization cycle, the vacuum pump 38 is operated to draw the vacuum in the sterilization chamber 30 back down to its original value. When the vacuum is returned to its original value, another pulse of hydrogen peroxide is injected into the sterilization chamber. This procedure of drawing a vacuum and injecting hydrogen peroxide is repeated a number of times until sterilization is complete. At that time, approximately forty minutes into the sterilization cycle, the sterilization chamber 30 is vented to atmosphere.

A block diagram illustrating the components of the control circuit 48 is illustrated in Figure 4. The control circuit 48 includes a first current source 70 for providing current to the first resistive element 18 and a second current source 72 for providing current to the second resistive element 12. The provision of current sources 70 and 72 for resistance temperature detectors 12 and 18 is well-known in the art. The signals produced by the first and second current sources 70 and 72 respectively, are input to a time multiplexor 74. These signals, which are representative of the temperatures T1 and T2, are alternately input to a sample and hold circuit 76. The output of the sample and hold circuit 76 is amplified by an amplifier 78. The amplified signal is converted to digital form by an analog to digital converter 80. The digital signals representative of the temperatures T1 and T2 are input to a microprocessor 82 through an input/output port 84. The microprocessor 82, operating according to instructions stored in a memory 86, controls the operation of the multiplexor 74, sample and hold circuit 76, and A/D converter 80 through the input/output port 84 in a known manner.

In operation, the microprocessor 82 enables the multiplexor 74 such that one of the temperature signals T1 and T2 is presented to the sample and hold circuit 76. The sample and hold circuit 76 holds that analog value for a sufficient period of time such that the analog to digital converter 80 converts the analog value into a digital value. That digital value is read into the microprocessor 82 which then repeats the process to input a value representative of the other temperature measurement.

In an embodiment wherein the pressure remains constant during the time period of interest, the pressure reading P on line 54 is used for purposes of performing a sterilization cycle such as the one illustrated in Figure 3 and is not needed for determining the concentration of the hydrogen peroxide vapour. As seen from equation (4) above, after the microprocessor 82 has read in values corresponding to the temperatures T1 and T2, the two temperatures are subtracted from one another to produce a temperature differential. The temperature differential is compared to an empirical data consisting of temperature differentials and corresponding hydrogen peroxide concentrations stored in memory 86. When a match is located, the hydrogen peroxide concentration corresponding to that temperature differential is selected by the microprocessor 82. At this point, the microprocessor 82 may display the selected hydrogen peroxide concentration by outputting a signal on line 66 to the indicator 68.

The selected value of the hydrogen peroxide concentration may also be compared by the microprocessor 82 to a set-point value to determine if the instantaneous concentration is either above or below the set-point value. If below, the microprocessor 82 may output a signal on line 56 to open valve 36 thereby enabling additional hydrogen peroxide to flow from the tank 32 to the sterilization chamber 30. If the instantaneous value of the

hydrogen peroxide is above the set-point value, then a signal may be output by the microprocessor 82 on line 60 to open valve 42 and a signal may be output on line 64 to begin operation of the vacuum pump 38 to remove hydrogen peroxide from the sterilization chamber 30. Alternatively, a signal may be output on line 62 to open valve 46 to enable hydrogen peroxide to flow out of the sterilization chamber 30 through vent line 44. In this manner, the microprocessor 82, using the raw data produced by the sensor 10, controls the concentration of the hydrogen peroxide in the sterilization chamber 30.

In the event that the pressure within the sterilization chamber 30 is not maintained constant during the time period of interest, then empirical data corresponding to the information required by equation (3) may be stored in the memory 86. The microprocessor 82 will take the raw temperature data representative of the temperature T1 and T2 together with the raw pressure data representative of the pressure P and compare those readings with the information stored in the memory 86. When there is a match between the measured temperatures T1 and T2 and measured pressure P with stored values for the temperatures T1 and T2 and the pressure P, the microprocessor 82 will select the corresponding hydrogen peroxide concentration. This selected concentration may be displayed by indicator 68 or compared with a set-point for controlling the system as described hereinabove. The hydrogen peroxide concentration may be determined as often as desired.

In addition to the functions just described, the microprocessor 82 causes the sterilization cycle shown in Figure 3 to be performed. For example, the microprocessor 82 periodically compares the temperature T1 with a reference temperature. In the event the temperature T1 falls below the reference temperature, the microprocessor 82 may output a signal on line 58 to energise heater 59 to thereby control the temperature in the sterilization chamber 30 according to the desired sterilization cycle. Additionally, the microprocessor 82 may use the signal representative of the pressure P in the sterilization chamber 30 to control the pressure. This can be accomplished by comparing the pressure signal P to various reference pressures followed by manipulation of the valves 36, 46, or 42, together with the vacuum pump 38 in order to control the pressure according to the desired sterilization cycle.

While the present invention has been described in connection with an exemplary embodiment thereof, many modifications and variations may be made. For example, sensors comprised of elements constructed of materials other than platinum may be used in combination with the sensing of other sterilants. Also, there are numerous schemes for inputting raw data to a microprocessor other than that illustrated in Figure 4.

CLAIMS

1. A sensor for producing a signal representative of the instantaneous amount of a concentrate in an environment comprising first means for producing a first signal representative of the temperature of the environment;

shield means for isolating said first means from the concentrate; and

second means including a material capable of interacting with the concentrate to modify the temperature sensed by said second means, said second means serving for producing a second signal representative of said modified temperature such that said first and second signals are representative of the instantaneous amount of the concentrate in the environment.

2. A sensor as claimed in claim 1, wherein said shield means includes a heat transmissive sealing means.

3. A sensor as claimed in claim 1 or 2, additionally comprising a substrate for carrying said first and second means such that, in the absence of the concentrate, said first and second means sense substantially the same temperature.

4. A sensor as claimed in claim 1, 2 or 3, wherein said first and second means include first and second resistive temperature detectors, respectively.

5. A sensor as claimed in any of claims 1 to 4, wherein said second means includes a platinum resistive element capable of interacting with a hydrogen peroxide concentrate.

6. A sensor as claimed in claim 5, wherein the amount of platinum is small, such that the ambient temperature measured by said first means is unaffected by the interaction of said platinum with the hydrogen peroxide.

7. A system for indicating the instantaneous amount of a concentrate in an environment, comprising:

a first resistive element isolated from the concentrate for producing a first signal representative of the temperature of the environment;

a second resistive element exposed to the concentrate and constructed of a material capable of interacting with the concentrate to modify the temperature sensed by said second resistive element, said second resistive element serving for producing a second signal representative of said modified temperature;

means responsive to said first and second signals for producing an output signal representative of the instantaneous amount of concentrate in the environment; and

output means responsive to said output signal.

8. A system as claimed in claim 7, additionally comprising first and second current sources for providing power for said first and second resistive elements, respectively.

9. A system as claimed in claim 7 or 8, wherein said means for producing an output signal includes a control circuit, and said system additionally comprises means for inputting said first and second signals to said control circuit.

10. A system as claimed in claim 9, wherein said means for inputting includes a time multiplexor, a sample and hold circuit, and an analog to digital converter, all serially connected and controlled by said control circuit.

11. A system as claimed in claim 9 or 10, wherein said control circuit includes means for subtracting said first and second signals from one another to produce differential temperature signals, memory means for storing empirical data containing differential temperature values together with corresponding values representative of amounts of the concentrate, and means for comparing said differential temperature signals to said stored differential temperature values.

12. A system as claimed in claim 9 or 10, additionally comprising a sensor for producing a pressure signal representative of the environmental pressure, and wherein said control circuit produces said output signal in response to said first and second signals and said pressure signal.

13. A system as claimed in claim 12, wherein said control circuit includes memory means for storing empirical data containing values for said first and second signals and said pressure signals together with corresponding values representative of amounts of the concentrate, and means for comparing said first and second signals and said pressure signal with said stored values.

14. A system for controlling the instantaneous amount of a concentrate in a chamber, comprising:

a first resistive element positioned in the chamber and isolated from the concentrate for producing a first signal representative of the temperature in the chamber;

a second resistive element exposed to the concentrate and constructed of a material capable of interacting with the concentrate to modify the temperature sensed by said second resistive element, said second resistive element serving for producing a second signal representative of said modified temperature, said first and second signals being representative of the instantaneous amount of concentrate in the chamber;

means for increasing the amount of concentrate in the chamber;

means for decreasing the amount of concentrate in the chamber; and

control means responsive to said first and second signals for producing output signals for controlling said means for increasing and said means for decreasing such that the instantaneous amount of the concentrate in the chamber is controlled.

15. A system as claimed in claim 14, wherein the chamber includes a sterilization chamber and wherein the concentrate includes hydrogen peroxide vapour.

16. A system as claimed in claim 15, wherein said means for increasing includes a source of hydrogen peroxide vapour connected to the chamber through a valve controlled by said control means.

17. A system as claimed in claim 14, 15 or 16, wherein said means for decreasing includes a vacuum pump connected to the chamber through a valve, said valve and said vacuum pump being controlled by said control means.

18. A system as claimed in claim 17, wherein said means for decreasing includes a vent pipe connected to the chamber through a valve controlled by said control means.

19. A sensor constructed and adapted to operate substantially as herein described with reference to and as illustrated in Figure 1 of the accompanying drawings.

20. A concentration indicating system constructed, arranged and adapted to operate substantially as herein described with reference to and as illustrated in the accompanying drawings.

21. A quantity controlling system constructed, arranged and adapted to operate substantially as herein described with reference to and as illustrated in the accompanying drawings.

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